

WORLD INTELLECTUAL PROPERTY ORGANIZATION International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 4:

(11) International Publication Number:

WO 90/06745

A61K 7/18, 9/70

A1

(43) International Publication Date:

28 June 1990 (28.06.90)

(21) International Application Number:

PCT/US88/04494

Published

ueu With international search report. With amended claims and statement.

(22) International Filing Date:

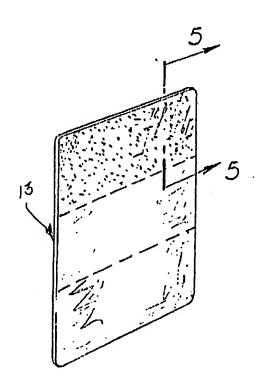
16 December 1988 (16.12.88)

(71)(72) Applicants and Inventors: COPELAN, James [US/US]; 121 W. Lexington Ave., Glendale, CA 91203 (US). CO-PELAN, Phoebe [US/US]; 121 W. Lexington Ave., Glendale, CA 91208 (US).

(74) Agent: WAGNER, John; Wagner & Middlebrook, 3541 Ocean View Blvd., Glendale, CA 91208 (US).

(81) Designated States: AT (European patent), AU, BE (European patent), CH (European patent), DE (European patent), FR (European patent), GB (European patent), IT (European patent), JP, LU (European patent), NL (European patent), SE (European patent).

(54) Title: DISPOSABLE PERSONAL DENTAL HYGIENE ASSEMBLY



(57) Abstract

An assembly having a membrane (13) comprising cellulose paper, either non-woven or of a loose weave and a fragmentary section (5) impregnated.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

TA	Austria	ES	Spain	MG	Madagascar
AU	Australia	Ħ	Finland	ML	Mali
BB	Barbados	FR	France	MR	Mauritania
BE	Belgium	GA	Gabon ·	MW	Malawi
BF	Burkina Fasso	GB	United Kingdom	NL	Netherlands
BG	Bulgaria	· HU	Hungary	NO	Norway
BJ	Benin	TT .	Italy	RO	Romania
BR	Brazil	JР	Japan	SD	Sudan
CA	Canada	KP	Democratic People's Republic	SE	Sweden
CF	Central African Republic		of Korea	SN	Senegal
CG	Congo	KR	Republic of Korea	SU	Soviet Union
CH	Switzerland	и	Liechtenstein	TD	Chad
CM	Cameroon	LK	Sri Lanka	TG	Togo
DE	Germany, Federal Republic of	w	Luxembourg	us	United States of America
DK	Denmark	MC	Monaco		

WO 90/06745 PCT/US88/04494

1

DISPOSABLE PERSONAL DENTAL HYGIENE ASSEMBLY

BACKGROUND OF THE INVENTION

One of the banes of the regular traveler or those working or engaging in sports and away from their residence is the maintenance of regular dental hygiene. particularly true for the traveler who may spend many hours without facilities or dental hygiene supplies, such as a toothbrush, dentifrice, mouthwash and dental floss. Most persons note after a few hours, an unpleasant feeling of known bacteria and plaque buildup which is usually accompanied by unpleasant breath, often undetected by the person directly but a condition or risk with which the person is acutely aware. This latter problem has given rise to the increasing popularity of spray type breath deodorizers and "breath mints". The users of such sprays or lozenges fully recognize that the effect is primarily cosmetic or masking and does not attack the real problem of bacteria and plaque removal nor does it provide any cleaning, polishing or improvement in the condition of the surfaces of the teeth, gums, tongue, and surrounding mucosa of the mouth.

There are four primary limitations to good oral hygiene practices away from home. The first is the unavailability of suitable water and disposal facilities for the actual process associated with the cleaning procedures. The second limitation is the lack of privacy

for the procedures of brushing, rinsing, expectoration and The third limitation is the lack of reasonable The fourth limitation is the lack of cleanliness. convenience of being able to perform the procedures. principal limitations to good dental hygiene away from home are exemplified by the plight of the business traveler. A 14-hour day of sales calls rarely, if ever, includes a suitable facility with water for brushing, rinsing, expectoration and clean-up. There are few private areas for such procedures. Even if such an area could be found, it is most likely to be in the restroom of a less than frequently cleaned road side filling station, usually inconvenient located, leading to the further frustration of being unable to accomplish any dental hygiene routine or procedure.

PRIOR ART

In the past, many attempts have been made to overcome the difficulties described above, but none have achieved any effective combination for dental hygiene procedures.

Exemplary of the prior art are the following:

U. S. Patent 2,527,931 H. Iskoe Oct. 31, 1950

A foldable, disposable toothbrush with a dentifrice in a cup which is dispensable in a coin operated vending machine.

U. S. Patent 4,384,645 J. A. Manfredi May 24, 1983

A portable kit with a toothbrush head which attaches a main hollow body and protected by a cover. The hollow handle encloses a supply of dentifrice.

U. S. Patent 3,646,628 G. C. Hulford Mar. 7, 1972

A foam plastic scrubber for teeth on the end of a plastic round stick. The end of the stick within the foam plastic is pointed and can be used as a tooth pick.

U. S. Patent 3,699,979 Muhler et al October 24,

A non-wax dental floss or tape impregnated with a specifically defined dental and polishing agent with a saliva soluble coating for improving the cleaning properties of dental floss.

U. S. Patent 4,554,154 M. White Nov. 19, 1985

A method and product for dental treatment employing a chewable plastic tape carrying an adhesive

4

with remineralizing, immunological and anti-bacterial agents. The adhesive is used to adhere to the teeth and prevent the attachment of plaque.

U. K. Patent 2,048,073 D. W. Kay Dec. 10, 1980

A water absorbing cloth sleeve for the finger impregnated with cleaning agent including a flavoring agent, a bleaching agent and/or a dental abrasive.

Swiss Patent 633,709 C. Beretta Dec. 12, 1982

A sealed foil packet containing a moistened terry

cloth like fabric impregnated with a liquid or paste

cleaning agent as a substitute for a tooth brush and tooth

paste.

Each of these approaches have made progress toward, but have not achieved a truly portable, effective, unobtrusive dental hygiene assembly which may be used comfortably in public, without the need for water as a carrier or for rinsing, with adequate privacy, in an acceptable clean, convenient embodiment to assure its use.

Other patents of ancillary interest include:

U. S. Patent 3,057,467 R. R. Williams Oct. 9, 1962

A sealed packet with a paper impregnated with alcohol and water for use in cleansing the hands and face. The patent covering the commercial "Wash'nDri" moist

5

disposable towelette.

- U. S. Patent 975,205 C. F. Booth Nov. 8, 1910

 A holder for a number of strands of dental floss.
- U. S. Patent 1,928,007 P Corsello Sept. 26, 1933

 A chewing gum wrapper using dental floss as a tear string.

6

BRIEF DESCRIPTION OF THE INVENTION

Recognizing the continuing need for an effective and socially acceptable assembly for use in public in performing regular dental hygiene, which was not dependant upon a water supply, secreted privacy, requiring clean individually prepared materials which would be convenient and readily used, in performing regular and periodic dental hygiene procedures, we examined the needs in greater detail. In doing so, we came to the conclusion that a dry, or nearly dry composition fabric of impregnated cleaning agents, dehydrated and/or impregnated upon and into a membrane, was needed to clean and polish the teeth and clean and refresh the gums, tongue and surrounding mucosa of the mouth. A truly useful system needs to rely upon the user's own saliva or the moisture present in the mouth or in unwanted plaque to provide the necessary vehicle to cause reconstitution of the various dehydrated cleaning, polishing, and freshening agents and for the purpose of limited migration throughout the mouth in use.

We also determined that the dry or near dry composition can be carried in a sealed, but not necessarily vapor tight bag or packet and remain effective for prolonged periods of storage. We further found that the cleaning and polishing ingredients may be effectively carried to the surface of the teeth, gums, tongue and surrounding mucosa of the mouth on a membrane in dry dehydrated or impregnated f rm with the relative dryness adding to the effectiveness of the polishing agent present.

WO 90/06745 PCT/US88/04494

7

For a membrane, we found that non-woven cellulose fabric of loose or open porosity is desired so that the membrane may be impregnated with a number of active ingredients in liquid form and subsequently dried for a dry, dehydrated, impregnated membrane of suitable size, e. g. 3 inch by 4 inch, to be partially placed in the mouth.

For a membrane, we likewise found that approximately thirty percent (30%) of the membrane should be saturated, dehydrated and impregnated with the active ingredients. The balance of the membrane should be dry and utilized for clean up of the slight residue if any that may be present upon the lips and finger tips, after use.

A finger, suitable stiff member or the tongue, can be used to massage clean and wipe the teeth, gums, tongue and surrounding mucosa of the mouth with the thirty percent (30%) saturated, dehydrated and impregnated portion of the membrane. There is normally sufficient saliva in the mouth to aid in cleaning and polishing or in accordance with this invention, a humectant may be dehydrated or impregnate within the membrane to aid in saliva generation.

The active ingredients which are dehydrated or impregnated within the membrane may include a flavor and color, however, it is the objective that the residue after cleaning be so slight that upon removal of the membrane, the user feels no need to expectorate or rinse their mouth but rather feels a pleasant fresh taste and feeling of having effectively cleansed their mouth.

In one embodiment, the membrane has secured to it a loop of dental floss which in its pre-formed loop form is ready for flossing, if the user desires. The end of the loop may extend out of the package to form a pull string opener.

In another embodiment, the membrane is in the form of a conical shape secured to a stick for cleaning much like moving a lollipop within the mouth. One surface is designed for polishing the teeth and another surface is particularly designed to massage the gums and deliver as the other embodiments, a dehydrated, impregnated combination of ingredients which are reconstituted by the moisture present in saliva, plaque and the surrounding mucosa of the mouth.

The term "dry" within the context of this invention means not only a total absence of liquid, including water, but the presence of such small amounts of liquid that the user need not expectorate or swallow noticeable liquid after use.

BRIEF DESCRIPTION OF THE DRAWING

This invention may be more clearly understood from the following detailed description and by reference to the drawing in which:

Fig. 1 is a perspective view of a packet of dental hygiene material in accordance with this invention;

Fig. 2 is a side elevational view of the packet of Fig. 1 with a portion broken away to show the contents;

Fig. 3 is a perspective view of the packet of Fig. 1, partially opened by tearing an edge;

Fig. 4 is a perspective view of the membrane contents of the packet of Figs. 1-3;

Fig. 5 is an enlarged fragmentary section of the membrane of Fig. 4 taken along lines 5-5 of Fig. 4; this embodiment of the invention employs a folded, thirty percent (30%) segmented by area, dehydrated impregnated membrane with a loop of dental floss attached. The 30% portion contains the dehydrated, impregnated materials and the remainder of the membrane is for cleaning off the residue, if any, which may be on the lips and/or finger tips area after use;

Fig. 6 is a perspective view of an alternate embodiment of this invention using a loop of dental floss as a tear string for the packet of Fig. 1;

Fig. 7 is a perspective view showing the use of the dental floss tear string to open the packet of Fig. 6;

Fig. 8 is a fragmentary perspective view of the membrane of Figs. 6 and 7 with a dental floss loop attached for use as a holder and for flossing;

Fig. 9 is a second alternative embodiment of this invention employing a folded, thirty percent (30%) segmented, dehydrated, impregnated membrane with a loop of dental floss attached to a stiffening member. The 30% portion contains the dehydrated, impregnated materials and the remainder of the membrane is for cleaning of the residue, if any, which may be on the lips and/or finger tips after use;

Fig. 10 is a perspective view of a third alternate embodiment of this invention employing a dehydrated, impregnated foam teeth cleaning device with a stick handle; and

Fig. 11 is a perspective view of the embodiment of Fig. 10 in its protective package.

DETAILED DESCRIPTION OF THE INVENTION

Now referring to Figs. 1-4, the virtual simplicity of this invention becomes apparent in that, as purchased, carried, ready for use, the invention appears as a simple, edge-sealed, packet 10 of protective material such as coated or uncoated paper which is adhesively or mechanically bonded at its edges 11 while forming a generally rectangular pouch 12 for Figs. 2 and 3. The packet 10 may be of foil or moisture impervious sheet plastic material but need not be so in the basic form of this invention. The packet has dimensions in the order of 1 by 4 inches and may have the general appearance of the hand washing packet of The Kendal Company of Boston, Massachussettes and sold under the trademark Wash'nDri.

By way of contrast from the Wash'nDri packet, this invention, in its preferred embodiment, is dry and intended for oral use in cleaning and polishing the teeth and for cleaning the gums, tongue, and surrounding mucosa of the mouth and in plaque removal, with the user's own mouth furnishing the only liquid required, which reconstitutes in situ, the ingredients which are dehydrated and/or impregnated within the membrane.

Contained within the packet 10 is the membrane 13 of Figs. 2 - 5 which may be characterized as a slightly abrasive cellulose paper, either non-woven or of a loose weave to present a highly porous structure as is illustrated in Fig. 5. Examples of satisfactory membranes are the following:

- 1). An unwoven cellulose fiber mat with an embossed striated texture of a weight range of 0.5 to 5 pounds per 100 square feet of surface area, machine cut into individual membranes of 3 inches by 4 inches, folded into thirds, with a packaged shape of 1 inch by 4 inches.
- 2). A similar sized and weight woven cotton fiber mat with an embossed striated texture.
- 3). A similar sized and weight woven cotton fiber gauze mat with an embossed striated texture.
- 4). A similar sized and weight polyester fiber gauze mat with an embossed striated texture.
- 5). A similar sized and weight cellulose, cotton, woven fiber, polyester blend mat with a striated texture.
- 6). A polystyrene or similar foam with a porous striated texture in sheet membrane form.
- 7). A polystyrene foam with a porous striated texture in a chisel/wedge shape with transverse grooves.

THE PREFERRED MEMBRANE BEING:

An unwoven cellulose fiber mat with an embossed striated texture of a weight range of 0.5 to 5 pounds per 100 square feet of surface area, machine cut into individual membranes of 3 inches by 4 inches, folded into thirds, with a packaged shape of 1 inch by 4 inches.

Dehydrated, impregnated within the membrane Fig. 4 are a number of compositions which may cooperate in an in situ

reconstitution of dehydrated, impregnated compositions, to form a totally effective dental hygiene procedure for:

- A) Removing plaque from the surface of the teeth, gums, tongue and surrounding mucosa in the mouth;
 - B) polishing the exposed surfaces of the teeth;
 - c) reducing the bacteria count in the mouth;
- D) neutralizing the cariogenic bacterial acids present in the mouth;
 - E) neutralizing the pH levels in the mouth;
- F) providing a slight pleasant taste in the mouth;
- G) providing a slight pleasant clean sensation in the mouth; and
 - H) reducing or eliminating breath odors.

Several combinations of the compositions may be impregnated within the membrane to achieve several of the above desirable results. They fall into the following classifications;

I. ANTI CARIES AGENT:

SODIUM FLUORIDE (NaF)

Active anti-caries agent: Sodium Fluoride an ionized fluoride ion, when placed on tooth surface (hydroxyapatite crystals or imperfect H.A. Crystals) forms insoluble fluorapatite. Sodium Fluoride is a white, odorless powder, used in fluoridation of water at 2% solution, to reduce the incidence of dental caries.

STANNOUS FLUORIDE (SNF2)

Active anti-caries agent: Stannous Fluoride, an ionized fluoride ion, when placed on the tooth surface (hydroxyapatite crystals or imperfect H.A. Crystals) forms insoluble fluorapatite. A compound containing not less than 71.2% stannus tin and between 22.3 and 25.5% fluoride.

II. ETCHING AGENT:

MONO AND DIBASIC SODIUM PHOSPHATES (Na2HPO4, 7H2O)

The deliberate acid etching of enamel surface prior to or at the same time as the application of ionized fluoride ion will free bonds from the hydroxyapatite, making available for the formation of fluorapatite crystals, thus a greater resistance to cariogenic bacteria.

WO 90/06745 PCT/US88/04494

15

III. ACID NEUTRALIZING AND PH REGULATING AGENT:

Sodium Bicarbonate acts as an acid neutralizing agent. Sodium Bicarbonate aids in the neutralization of plaque acids found on the surface of the teeth, gums, tongue and surrounding mucosa of the oral cavity that produce caries.

IV. CLEANING, POLISHING AND DEODORIZING AGENT:

Sodium Bicarbonate also is a preferred agent to act as a cleaning, polishing and deodorizing agent. Sodium Bicarbonate acts as a mild abrasive for cleaning and polishing the teeth.

V. STABILIZING AGENT:

POLOXAMER 407 functions as a surfactant, emulsifier or stabilizing agent. Poloxamer 407 is one of a series of non-ionic surfactants of the polyoxypropylene-polyoxyethylene copolymer type sold by the Johnson & Johnson Company of New Jersey.

VI. SURFACTANT AGENT:

POLOXAMER 407 also functions as a surfactant.

VII. EMULSIFIER AGENT:

POLOXAMER 407 is effective to function as an emulsifier or stabilizing agent.

VIII. FLAVOR BLENDING AGENT/SWEETENER:

SODIUM SACCHARIN (C7H4N Na03A, 2H20) Sodium Saccharin is a calcium salt sweetener which reduces the saltiness of the sodium bicarbonate and other ingredients.

IX. FLAVORING AGENT:

Peppermint acts as a flavoring agent for purposes of providing a pleasant mild flavor which aids in favorable and frequent use.

X. COLORING AGENT:

FD & C RED COLOR #6 AND #33 act as a coloring agent for purposes of providing a pleasant color without leaving any color trace on the teeth and mouth when used in trace quantities.

XI. ALKALIZING AND EXPECTORANT:

SODIUM ACETATE functions as an alkalizing and expectorant agent. Sodium Acetate is a sodium salt which promotes the ejection (loosening) of mucous or exudate and also acts as an alkalizing agent for anti-cariogenic purposes.

WO 90/06745 PCT/US88/04494

17

XII. ANTI CAKING AGENT:

MAGNESIUM OXIDE (Mg0) Functions as an anti-caking agent. Magnesium oxide is used as a sorbent (attracts and retains substances by absorption) which aids in the free-flow and anti-caking of other ingredients.

XIII. LUBRICATING AGENT:

MAGNESIUM SILICATE functions as a lubricating agent and is used as a lubricant in conjunction with Magnesium Oxide and as a suspending agent.

XIV. MEMBRANE:

The membrane is of a non-woven cellulose fiber and/or a cotton cloth/gauze, of a size of three (3) inches by four (4) inches which by itself will remove plaque with mechanical manipulation against the teeth, gums, tongue and surrounding mucosa of the oral cavity. The membrane is impregnated by dehydrated or slightly dehydrated materials selected from the group above to increase its effectiveness.

XV. LIQUID CARRYING AGENTS:

Water, alcohol, glycerin and/or mineral oil based solutions are suitable carriers for saturation, impregnation and deposition of the above agents upon and into the membrane prior to removal of the liquid carrying agent by evaporation.

PREFERRED COMBINATION OF INGREDIENTS FOR IMPREGNATION OF MEMBRANE

The preferred combination of materials is as follows with an explanation of the functions of each material and why the product increases in effectiveness with the addition of each additional material.

1). MEMBRANE

The membrane is of a non-woven cellulose fiber and/or cotton cloth/gauze, which by itself has slight abrasive qualities to remove plaque with mechanical manipulation against the teeth, gums, tongue and surrounding mucosa of the oral cavity. The membrane is impregnated with the following materials to increase its effectiveness..

2). SODIUM FLUORIDE Acidulated Fluoride.

Sodium Fluoride, when added to the membrane, acts as the anti-caries agent. The well known mechanisms of sodium fluoride are 1) the reduction of apatite solubility through conversion of hydroxy-apatite to fluorapatite, 2) remineralization of carious lesions with the deposition of fluoride salts, and 3) antimicrobial activity. The mineral phase of dental enamel is spoken of as hydroxyapatite (Ca10, (PO4)6, (OHO2). Hydroxyapatite is however, usually impure to some degree from the acids and bacteria in one's system. The addition of sodium fluoride to the impure hydroxyapatite forms fluorapatite which is relatively insoluble and adds to enamel/tooth strength. Fluoride

salts further act on demineralization enamel (carries/decay) by remineralizing that enamel in early carious lesions. Lastly, the fluoride ion in sodium fluoride influences the plaque microbial ecology. The inhibition of sugar metabolism reduces acidogenises with a decrease in enamel demineralization and interference with the plaque polysaccharide formation resulting in a decrease of microbial adhesions to the tooth surface.

3). STANNUS FLUORIDE

With the addition of stannous fluoride, the anticaries agent and properties are enhanced further. The
stannous ion contributes to the formation of the
fluorapatite complex and relatively insoluble salts of
tin. The stannus ion (salts) make a significant
contribution to the arrestment of existing caries lesions.

4). MONO AND DIBASIC PHOSPHATES (Acidulated Phosphate)

When the phosphate ion is added to the membrane, in conjunction with the fluoride ions, it acts as an acid etching agent. The understanding is that the excess phosphate ions would drive the mineral equilibrium of enamel surface toward mineralization with maximum fluorapatite formation. This acid etching of the enamel surface will free some of the weaker bonds of the hydroxyapatite making deficient crystals available to form with the fluoride ions and fluorapatite formation. The increase in fluorapatite crystals on the enamel surface

allows a greater resistance of cariogenic attack.

5). SODIUM BICARBONATE

When sodium bicarbonate is added to the membrane, it acts as a cleaning, acid mineralizing, polishing and deodorizing agent. It is true that the membrane itself function as a polishing vehicle however, with the addition of sodium bicarbonate, there is present a mild abrasive impregnated onto the membrane surface which further enhances the plaque removal. The cleaning and polishing agent of sodium bicarbonate is due to the low abrasive crystals which are very soft and partially soluble in saliva. The solubility of sodium bicarbonate further acts as an acid mineralizing agent by having the ability to neutralize both acid and bases to produce salts and water. The result is a powerful buffer which helps in regulating the pH of the oral cavity and neutralizes plaque acids which are responsible for carious lesions. Studies have shown that a reduced level of bicarbonate ions in the saliva show an increased incidence of dental caries. Finally, the sodium bicarbonate ions acts as a deodorizing agent through the balance of pH.

6). POLOXAMER 407

The function of poloxamer 407 is to act as a surfactant (surface agent) agent. This aids in the loosening of the plaque for easier removal that is on the surface of the teeth, gums, tongue, and surrounding mucosa of the oral cavity.

7). SODIUM SACCHARIN

The addition of sodium saccharin to the membrane provides a sweetener by reducing the saltiness due to the sodium bicarbonate. As previously mentioned, sodium bicarbonate neutralizes acids in the oral cavity to balance pH, which forms salts and water. Sodium saccharin thus aids in reducing the salt flavor when added to the membrane aiding in favorable and frequent use.

8). SORBITOL/MANNITOL

As an alternative to the use of sodium saccharin, the addition of sorbitol/mannitol to the membrane acts similarly as a sweetener by reducing the saltiness of the sodium bicarbonate. Sorbitol/mannitol are sugar alcohols that are generally not absorbed well by the body. These ingredients resist the bacterial action of the oral cavity as well and are non-cariogenic. Additionally, as previously mentioned, sodium bicarbonate neutralizes acids in the oral cavity to balance pH, which forms salts and water. Sorbitol/mannitol thus aids in reducing the salt flavor when added to the membrane, aiding in favorable and

frequent use.

9). ASPARTAME

As an alternate, Aspartame may be substituted for sodium saccharin or sorbitol/mannitol. The addition of Aspertame to the membrane acts as a sweetener by reducing the saltiness of the sodium bicarbonate. This ingredient resists the bacterial action of the oral cavity as well and is no-cariogenic. Aspartame aids in reducing the salt flavor when added to the membrane, aiding in favorable and frequent use.

10). SORBIC ACID

The addition of sorbic acid to the ingredients functions and acts as a preservative agent for the antimicrobial mechanisms of the sodium fluoride and stannous fluoride. The antimicrobial mechanisms again aid in the inhibition of sugar metabolism thus reducing the amount of acids in the oral cavity and decreases enamel demineralization.

11). SODIUM ACETATE

Sodium acetate may be added to the ingredients to function as an alkalizing and expectorant agent. The sodium acetate is a sodium salt which promotes the ejection (loosening) of mucous or exudate and also acts as an alkalizing agent. The s dium acetate influences the saliva form a sticky, cavity producing state to a thinner

state. When the saliva is in a thick consistency there is a greater adherence of bacteria to the surface of the teeth, gums, tongue and surrounding mucosa of the oral cavity, with an increase in tooth demineralization.

12). MAGNESIUM OXIDE

Magnesium oxide may be added to the ingredients to act as an anti-caking and free flowing agent. This allows the other ingredients to work together without being a sticky substance. Since the active ingredients are deposited on the membrane and mobility is the result largely of manual manipulation and dissolving of the ingredients in saliva, an anti-caking agent is usually not required but may be an optional component of the impregnated material.

13). MAGNESIUM SILICATE

Magnesium silicate added to the ingredients functions in conjunction with the magnesium oxide (if present) as a lubricating agent. When the membrane impregnated material is placed on the surface of the teeth, gums, tongue and surrounding mucosa of the oral cavity, and the functions of each ingredient is performed as previously explained, the magnesium oxide and magnesium silicate lubricate the surface of the teeth, gums, tongue and surrounding mucosa of the oral cavity to give them a refreshing feeling.

14). PEPPERMINT FLAVOR (FD & C #6 and #33)

The peppermint or other flavoring and coloring agent may be added to the above ingredients to provide a pleasant flavor and appealing color. When the impregnated membrane is wiped upon the surface of the teeth, gums, tongue and surrounding mucosa of the oral cavity, the peppermint flavor will aid in pleasant and fresh breath thus aiding in favorable and frequent use.

15). WATER/GLYCERIN/OIL VEHICLE

Water, glycerin or mineral oil are added to the ingredients which act as the vehicle for the ingredients to be applied to the membrane. Once applied, the evaporation or partial evaporation of the vehicle will impregnate the membrane with the above listed ingredients and then be allowed to function as mentioned and described.

PREFERRED EMBODIMENT

In the preferred embodiment of this invention, a cellulose paper membrane is used in a 3 x 4 inch sheet which weighs between 0.5 and 2.0 gms prior to impregnation with the materials. Typically the total weight of the materials added to the membrane ranges from 0.2 to 0.5 gms, made up approximately half and half sodium bicarbonate and flavoring, e. g. peppermint with the remaining agents and compounds present only in trace amounts.

PREFERRED PROCESS

The preferred process for impregnating the membrane is the dip and dry method. In a container holding approximately 250 ml of water, 1 oz. of commercial oil of peppermint, 3 tbs. of sodium bicarbonate plus four drops of food coloring were mixed and a paper membrane partially immersed for a few seconds in the bath. The membrane is withdrawn, dried in a warm commercial household dryer for a minute or two. The dried membrane was removed, folded and ready for packaging. Physically, the membrane shows a pink trace on the portions which were impregnated. The impregnated portion is slightly gritty as compared to the unimpregnated portion.

The other trace ingredients may be added to the water solution.

As an alternate process, the membrane may be passed through a dry bath of the materials and mechanically impregnated as by a pressure roller. The solution including the liquid vehicle plus the materials may be sprayed on the surface of the membrane or transferred by a blotting process.

The dip/dry method is preferred.

ALTERNATE COMBINATIONS OF INGREDIENTS FOR IMPREGNATION OF THE MEMBRANE:

Alternate combination #2

Membrane

Sodium Fluoride (0.05%) Active Ingredient

Vehicle

Glycerin,

Water or

Alcohol (6%)

Poloxamer 338

Poloxamer 407

Sodium Benzoate

Sweetener

Sodium Saccharin,

Sorbitol/Mannitol or

Aspertame

Benzoic Acid

Peppermint Flavoring

Coloring (FD & C Red #6 and #33)

Coloring (FD & C Blue #1, FD & C Yellow #5)

WHAT IS CLAIMED:

1. A disposable personal dental hygiene assembly comprising:

a porous membrane of sufficiently small size to fit into the mouth and to cover an area of the surface of the teeth;

said membrane including one area thereof impregnated with and carrying in dry form one or more of:

- a. AN ANTI CARIES AGENT
- b. AN ETCHING AGENT
 - c. AN ACID NEUTRALIZING AGENT
 - d. A CLEANING AGENT
 - e. A POLISHING AGENT
 - f. A DEODORIZING AGENT
 - g. A pH REGULATOR AGENT
 - h. A STABILIZING AGENT
 - i. A SURFACTANT AGENT
 - j. AN EMULSIFIER AGENT
 - k. A FLAVOR BLENDING AGENT/SWEETENER
 - 1. A FLAVORING AGENT
 - m. A COLORING AGENT
 - n. AN ALKALIZING AGENT
 - o. AN EXPECTORANT AGENT
 - p. AN ANTI CAKING AGENT
 - q. A LUBRICATING AGENT

to be effective in personal dental hygiene while in the presence of normal oral cavity moisture.

2. An assembly in accordance with claim 1 including a packet for enclosing said impregnated membrane;

said membrane enclosed in said packet for carrying by the intended user and for manual opening for use of the membrane;

said packet to be used by the intended user of the membrane for disposal of the membrane and packet.

- 3. A disposal personal dental hygiene assembly in accordance with Claim 1 where in said assembly includes a length of dental floss secured to said membrane.
- 4. A disposal personal dental hygiene in accordance with claim 2 wherein said dental floss incudes a portion extending out of said packet for use a tear string for said packet.
- 5. A personal dental hygiene assembly in accordance with claim 1 wherein said membrane comprises a foam plastic.
- 6. A personal dental assembly in accordance with Claim 4 wherein said foam plastic membrane is secured to a handle.

- 7. A personal dental assembly in accordance with Claim 1, including an anti-caries agent wherein said anticaries agent is selected form the group consisting of Sodium Fluoride and Stannous Fluoride.
- 8. A disposable personal dental hygiene assembly in accordance with Claim 1, including an etching agent, wherein said etching agent is selected from the group consisting of mono sodium and dibasic sodium phosphates.
- 9. A personal dental hygiene assembly in accordance with Claim 1, including an acid neutralizing agent, wherein said acid neutralizing agent is sodium bicarbonate.
- 10. A personal dental hygiene assembly in accordance with Claim 1, including a cleaning agent, wherein said cleaning agent is sodium bicarbonate.
- 11. A disposable dental hygiene assembly in accordance with claim 1, including a polishing agent, wherein said polishing agent is sodium bicarbonate.
- 12. A disposable dental hygiene assembly in accordance with claim 1, including a deodorizing agent, wherein said deodorizing agent is sodium bicarbonate.

- 13. A disposable dental hygiene assembly in accordance with claim 1, including a pH regulator agent, wherein said pH regulator agent is sodium bicarbonate.
- 14. A disposable dental hygiene assembly in accordance with claim 1, including a stabilizing agent, wherein said stabilizing agent is Poloxamer 407.
- 15. A disposable dental hygiene assembly in accordance with claim 1, including a surfactant agent, wherein said surfactant agent is Poloxamer 407.
- 16. A disposable dental hygiene assembly in accordance with claim 1, including an emulsifier agent, wherein said emulsifier agent is Poloxamer 407.
- 17. A disposable dental hygiene assembly in accordance with claim 1, including a flavor blending agent/sweetener, wherein said flavor blending agent/sweetener is sodium saccharin sorbitol/mannitol and aspertame.
- 18. A disposable dental hygiene assembly in accordance with claim 1, including a flavoring agent, wherein said flavoring agent is peppermint.

- 19. A disposable dental hygiene assembly in accordance with claim 1, including a coloring agent, wherein said coloring agent is FD & C Red #6 and #33.
- 20. A disposable dental hygiene assembly in accordance with claim 1, including an alkalizing agent, wherein said alkalizing agent is sodium acetate.
- 21. A disposable dental hygiene assembly in accordance with claim 1, including an expectorating agent, wherein said expectorating agent is sodium acetate.
- 22. A disposable dental hygiene assembly in accordance with claim 1, including an anti-caking agent wherein said anti-caking agent is magnesium oxide.
- 23. A disposable dental hygiene assembly in accordance with claim 1, including a lubricating agent wherein said Lubricating Agent is magnesium silicate.
- 24. A disposable dental hygiene assembly in accordance with claim 1 wherein said membrane is of a non-woven cellulose fiber which by itself will remove plaque with mechanical manipulation against the teeth, gums, tongue and surrounding mucosa of the oral cavity.

- 25. A disposable dental hygiene assembly in accordance with claim 1 wherein said membrane is woven fibrous material which by itself will remove plaque with the mechanical manipulation against the teeth, gums, tongue and surrounding mucosa of the oral cavity, the membrane has one portion impregnated with cleaning, polishing, anti caries, flavoring, acid neutralizing, alkalizing and coloring agents on a portion thereof, leaving the remaining portion of the membrane free of impregnated material for purposes of cleaning the lips and finger tips after use.
- 26. A disposable dental hygiene assembly in accordance with claim 1 wherein said membrane is a fibrous mat material which by itself will remove plaque with the mechanical manipulation against the teeth, gums, tongue and surrounding mucosa of the oral cavity, the membrane is only partially impregnated with a composition including a cleaning, polishing, anti caries, flavoring, acid neutralizing, alkalizing and coloring agents on a portion of thereof, which compositions reconstitute in situ upon contact with the moisture present on the teeth, gums, tongue and surrounding mucosa of the oral cavity and leaving the remaining portion of the membrane free of dehydrated material for purposes of cleaning the lips and finger tips after use.

- 27. A disposable dental hygiene assembly in accordance with claim 1 wherein said membrane is foam which by itself will remove plaque with the mechanical manipulation against the teeth, gums, tongue and surrounding mucosa of the oral cavity, the membrane is only partially impregnated with a composition including a cleaning, polishing, anti caries, flavoring, acid neutralizing, alkalizing and coloring agents on a portion of thereof, which compositions reconstitute in situ upon contact with the moisture present on the teeth, gums, tongue and surrounding mucosa of the oral cavity and leaving the remaining portion of the membrane free of dehydrated material for purposes of cleaning the lips and finger tips after use.
- 28. The method for producing a disposable personal dental hygiene device comprising:

preparing in a liquid vehicle a mixture of a normally dry mild abrasive plus a flavor;

exposing a porous membrane to the liquid vehicle to impregnate the pores and surface of the porous membrane with the mixture; and

drying the porous membrane whereby the membrane acts as a carrier for the mixture of mild abrasive plus flavor;

whereby said impregnated porous membrane may be carried in its dry form and used as a disposable personal dental hygiene device.

- 29. The method in accordance with Claim 28 including the step of adding one or more of the following ingredients to said mixture in trace amounts:
 - a. AN ANTI CARIES AGENT
 - b. AN ETCHING AGENT
 - c. AN ACID NEUTRALIZING AGENT
 - d. A CLEANING AGENT
 - e. A POLISHING AGENT
 - f. A DEODORIZING AGENT
 - g. ph regulator agent
 - h. A STABILIZING AGENT
 - i. A SURFACTANT AGENT
 - j. AN EMULSIFIER AGENT
 - k. A FLAVOR BLENDING AGENT/SWEETENER
 - 1. A FLAVORING AGENT
 - m. A COLORING AGENT
 - n. AN ALKALIZING AGENT
 - O. AN EXPECTORANT AGENT
 - p. AN ANTI CAKING AGENT
 - q. A LUBRICATING AGENT
- 30. The method in accordance with Claim 28 wherein said membrane is exposed to said liquid vehicle by immersion therein.
- 31. The method in accordance with Claim 28 wherein said membrane is exposed to said liquid vehicle by exposure to a spray of said liquid vehicle and mixture.

- 32. The method in accordance with Claim 28 wherein said membrane is exposed to said liquid vehicle by blotting.
- 33. The method for producing a disposable personal dental hygiene device comprising:

mixing a dry mild abrasive powder with a flavoring agent; and

impregnating the pores of a porous membrane with the results of the mixing;

whereby the impregnated membrane may be used as a disposable personal dental hygiene device.

- 34. The method in accordance with Claim 33 wherein the impregnation of the pores of the membrane is accomplished by mechanical pressure.
- 35. The method in accordance with Claim 33 wherein the mixing step includes the addition of one or more of the following:
 - a. AN ANTI CARIES AGENT
 - b. AN ETCHING AGENT
 - c. AN ACID NEUTRALIZING AGENT
 - d. A CLEANING AGENT
 - e. A POLISHING AGENT
 - f. A DEODORIZING AGENT
 - g. pH REGULATOR AGENT
 - h. A STABILIZING AGENT
 - i. A SURFACTANT AGENT
 - j. AN EMULSIFIER AGENT

- k. A FLAVOR BLENDING AGENT/SWEETENER
- 1. A FLAVORING AGENT
- m. A COLORING AGENT
 - n. AN ALKALIZING AGENT
 - o. AN EXPECTORANT AGENT
 - p. AN ANTI CAKING AGENT
 - q. A LUBRICATING AGENT.

Claim 1 specifies that the membrane is in <u>sheet</u> form and for rubbing finger pressure against the surface of the teeth and oral cavity. Claim 1 also specifies that plaque removal and tooth polishing are effected by the action using the sheet.

Claim 3 which adds a dental floss attachment points out that the dental floss is for inter-teeth cleansing. This claim defines a new combination of the sheet-like membrane for surface cleansing and polishing plus the floss. The floss provides a "handle" for opening the enclosing packet and a string for grasping while the sheet is manipulated in the mouth by the finger providing real inventive cooperation when flossing, the sheet provides a good grasping point for the floss.

Claim 6 has been amended to change the dependency from Claim 4 to Claim 5.

Claim 17 has been amended to true "Markush" type format.

The claims all distinguish the invention form the various dental floss disclosure whether thread-like or tape (Ashton), sutures (Novak) or such professional dental apparatus as gingerial yarn (Bell) or fibre (Goodson) or pad (Warren, Jr.) or implants (Corrnut, et al) for inter-tooth applications.

Likewise, the sheet assembly is not a chewing gum or other chewable product as in Werft, et al, Gunther or White.

The dry impregnated sheet is ideal for carrying in a sealed packet.

AMENDED CLAIMS

[received by the International Bureau on 03 August 1989 (03.08.89); original claims 1,3,6 and 17 amended; other claims unchanged (4 pages)]

1. A disposable personal dental hygiene assembly comprising: a porous membrane sheet of sufficiently small size to fit into the mouth and to be rubbed by the finger over areas of the surface of the teeth to remove plaque deposits thereon;

said membrane including one area thereof impregnated with and carrying in dry form one or more of:

- a. AN ANTI CARIES AGENT
- b. AN ETCHING AGENT
- c. AN ACID NEUTRALIZING AGENT
- d. A CLEANING AGENT
- e. A POLISHING AGENT
- f. A DEODORIZING AGENT
- g. A ph regulator agent
- h. A STABILIZING AGENT
- i. A SURFACTANT AGENT
- j. AN EMULSIFIER AGENT
- k. A FLAVOR BLENDING AGENT/SWEETENER
- 1. A FLAVORING AGENT
- m. A COLORING AGENT
- n. AN ALKALIZING AGENT
- O. AN EXPECTORANT AGENT
- p. AN ANTI CAKING AGENT
- q. A LUBRICATING AGENT

whereby plaque deposits on the surface of the teeth may be removed and the surface of the teeth may be polished while in the presence of normal oral cavity moisture.

2. An assembly in accordance with claim 1 including a packet for enclosing said impregnated membrane;

said membrane enclosed in said packet for carrying by the intended user and for manual opening for use of the membrane;

said packet to be used by the intended user of the membrane for disposal of the membrane and packet.

- 3. A disposal personal dental hygiene assembly in accordance with Claim 1 where in said assembly includes a length of dental floss secured to said membrane for use in flossing the v=crevices between the teeth.
- 4. A disposal personal dental hygiene in accordance with claim 2 wherein said dental floss incudes a portion extending out of said packet for use a tear string for said packet.
- 5. A personal dental hygiene assembly in accordance with claim 1 wherein said membrane comprises a sheet of foam plastic.
- 6. A personal dental assembly in accordance with Claim 5 wherein said sheet of foam plastic membrane is secured to a handle.

- 7. A personal dental assembly in accordance with Claim 1, including an anti-caries agent wherein said anti caries agent is selected form the group consisting of Sodium Fluoride and Stannous Fluoride.
- 8. A disposable personal dental hygiene assembly in accordance with Claim 1, including an etching agent, wherein said etching agent is selected from the group consisting of mono sodium and dibasic sodium phosphates.
- 9. A personal dental hygiene assembly in accordance with Claim 1, including an acid neutralizing agent, wherein said acid neutralizing agent is sodium bicarbonate.
- 10. A personal dental hygiene assembly in accordance with Claim 1, including a cleaning agent, wherein said cleaning agent is sodium bicarbonate.
- 11. A disposable dental hygiene assembly in accordance with claim 1, including a polishing agent, wherein said polishing agent is sodium bicarbonate.
- 12. A disposable dental hygiene assembly in accordance with claim 1, including a deodorizing agent, wherein said deodorizing agent is sodium bicarbonate.

- 13. A disposable dental hygiene assembly in accordance with claim 1, including a pH regulator agent, wherein said pH regulator agent is sodium bicarbonate.
- 14. A disposable dental hygiene assembly in accordance with claim 1, including a stabilizing agent, wherein said stabilizing agent is Poloxamer 407.
- 15. A disposable dental hygiene assembly in accordance with claim 1, including a surfactant agent, wherein said surfactant agent is Poloxamer 407.
- 16. A disposable dental hygiene assembly in accordance with claim 1, including an emulsifier agent, wherein said emulsifier agent is Poloxamer 407.
- 17. A disposable dental hygiene assembly in accordance with claim 1, including a flavor blending agent/sweetener, wherein said flavor blending agent/sweetener is selected from the group consisting of sodium saccharin sorbitol/mannitol and aspertame.
- 18. A disposable dental hygiene assembly in accordance with claim 1, including a flavoring agent, wherein said flavoring agent is peppermint.

3

-42-

STATEMENT UNDER ARTICLE 19

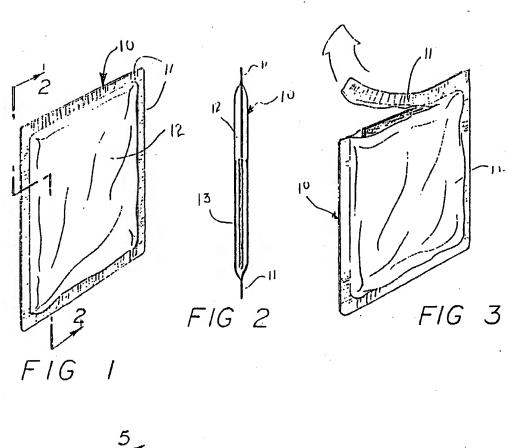
Claim 1 specifies that the membrane is in <u>sheet</u> form and for rubbing finger pressure against the surface of the teeth and oral cavity. Claim 1 also specifies that plaque removal and tooth polishing are effected by the action using the sheet.

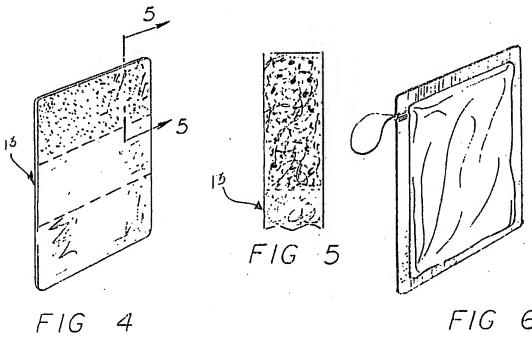
Claim 3 which adds a dental floss attachment points out that the dental floss is for inter-teeth cleansing. This claim defines a new combination of the sheet-like membrane for surface cleansing and polishing plus the floss. The floss provides a "handle" for opening the enclosing packet and a string for grasping while the sheet is manipulated in the mouth by the finger providing real inventive cooperation when flossing, the sheet provides a good grasping point for the floss.

Claim 6 has been amended to change the dependency from Claim 4 to Claim 5.

Claim 17 has been amended to true "Markush" type format.

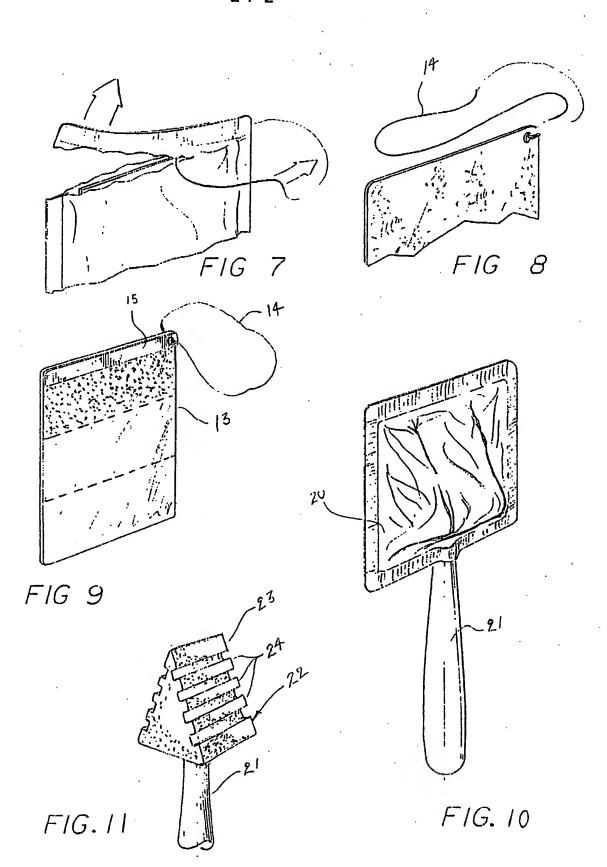
1/2





. 5

2/2



INTERNATIONAL SEARCH REPORT

International Application No. PCT/US88/04494

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) 6	US88/U4494		
According to International Patent Classification (IPC) or to both National Classification and IPC			
IPC(4): A61K 7/18 ; A61K 9/70.			
US. CL. 424/435			
II. FIELDS SEARCHED			
Minimum Documentation Searched ? Classification System			
Classification System Classification Symbols			
U.S. 132/93; 424/49, 52, 53, 57, 424, 425, 43 446; 132/93; 514/835, 900, 901, 902	5, 443,.		
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched			
· · · · · · · · · · · · · · · · · · ·			
III. DOCUMENTS CONSIDERED TO BE RELEVANT 9			
Category • Citation of Document, 11 with indication, where appropriate, of the relevant passages 12	Relevant to Claim No. 13		
X US, A, 2,700,636 (ASHTON) 25 JANUARY 1955 SEE THE FNTIRE DOCUMENT.	1-35		
X US, A, 2,748,774 (NOVAK) 05 JUNE 1956 SEE THE ENTIRE DOCUMENT.	1-35		
X US, A, 2,991,224 (BELL) 04 JULY 1961 SEE THE ENTIRE DOCUMENT.	1-35		
X US, A, 3,071,476 (WERFT) 01 JANUARY 1963	1-35		
SEE THE ENTIRE DOCUMENT.			
X US, A, 3,203,097 (HOLLANDER) 31 AUGUST 1965 SEE THE ENTIRE DOCUMENT.	1-35		
X US, A, 3,754,332 (WARREN, JR) 28 AUGUST 1973 SEE THE ENTIRE DOCUMENT.	1-35		
X US, A, 3,896,812 (KURTZ) 29 JULY 1975 SEE THE ENTIRE DOCUMENT.	1-35		
X US, A, 4,020,558 (COURNUT) 03 MAY 1977 SEE THE ENTIRE DOCUMENT.	1-35		
* Special categories of cited documents: 10 "T" later document published after the international filing date			
"A" document defining the general state of the art which is not considered to be of particular relevance or priority date and not in conflict with the application but cited to understand the principle or theory underlying the			
"E" earlier document but published on or after the international filling date "X" document of particular relevance; the claimed invention			
"L" document which may throw doubts on priority claim(s) or which is clied to exhalic the priority claim(s) or involve an inventive step			
citation or other special reason (as specified)			
"O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but			
later than the priority date claimed "4" document member of the same patent family IV. CERTIFICATION			
Poly of the April 10			
Date of Mailing of this International Search O 8 MAY 1989			
International Searching Authority Signature of Authorized Officer			
SA/US T. K. PAGE			

International Application No. PCT/US88/04494

III. DOCU	MENTS C NSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET	n .
Category *	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No
	- Designating that installed appropriate of the second	
x	US, A, 4,175,326 (GOODSON) 27 NOVEMBER 1979 SEE THE ENTIRE DOCUMENT.	1-35
x	US, A, 4,243,655 (GUNTHER) 06 JANUARY 1981	1-35
x	US, A, 4,554,154 (WHITE) 19 NOVEMBER 1985	1-35
	SEE THE ENTIRE DOCUMENT.	
	·	·
	· ie	
	·	
	·	
	,	
		1